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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,448	02/27/2004	Hiroshi Kido	02-0187	9915
28502	7590	08/12/2009	EXAMINER	
MICHAEL P. MORRIS			FOLEY, SHANON A	
BOEHRINGER INGELHEIM USA CORPORATION				
900 RIDGEURY ROAD			ART UNIT	PAPER NUMBER
P. O. BOX 368				1619
RIDGEFIELD, CT 06877-0368				
NOTIFICATION DATE		DELIVERY MODE		
08/12/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/790,448	KIDO, HIROSHI	
	<b>Examiner</b>	<b>Art Unit</b>	
	SHANON A. FOLEY	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 April 2009.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/30/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

The Group and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1619, Examiner Foley.

The 102 rejection based on the teachings of Mitra et al. is dropped due to the newly added limitations to instant claim 14.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on April 30, 2009 was filed after the mailing date of the non-final office action on December 11, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting proliferation of the influenza virus, does not reasonably provide enablement for preventing an influenza virus infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is maintained for reasons of record.

Claim 14 has been amended to state that the composition is administered in such an amount to promote secretion of antiviral factors in the respiratory tract. There is insufficient guidance provided in the disclosure for the skilled artisan to determine what this amount would correspond to or how to promote sufficient secretion of antiviral factors to prevent influenza virus infection.

Applicant discusses the prosecution history and maintains that the instant invention is enabled for the instant method of preventing influenza virus infection by administering effective amounts of ambroxol and/or bromhexin, and/or equivalent pharmaceutical salts and an additive. Applicant states that it is unclear why the *Molecular Cell Biology* reference is relevant to the instant invention. Applicant also cites MPEP § 2164.08, and emphasizes that the only relevant concern under enablement should be whether the scope of the knowledge provided to one skilled in the art is commensurate in scope with the protection sought by the instant claim.

The examiner concurs with applicant's assessment of MPEP § 2164.08. In the instant case, the claim is not commensurate in scope with the knowledge possessed by one skilled in the art. The scope of the instant claim is drawn to "preventing influenza virus infection" by administering particular ingredients or combinations of ingredients. There is no knowledge provided to one skilled in the art via the instant disclosure, the working examples or current state of the art that teaches how to completely inhibit a single virion from entry into one cell, which is encompassed by the instant scope of the claim. A broader scope of interpretation, which would be pre-symptomatically inhibiting influenza virus infection in any host, is also not adequately described in the instant disclosure, working examples or state of the prior art. Therefore, it is

clear that the discussion provided in *Molecular Cell Biology* is definitely pertinent and a thorough analysis under MPEP § 2164.08 is required in the instant case.

Applicant discusses the teachings of Benne et al., submitted in the IDS and concludes that SP-A can neutralize flu viruses. Applicant asserts that since ambroxol increases the quantity of surfactants, such as SP-A, one skilled in the art would have sufficient guidance to practice the instant invention.

Applicant's arguments and a full review of the teachings of Benne have been considered, but are found unpersuasive for several reasons. It is noted that Benne only discusses the binding of SP-A to influenza virus A, see the abstract and Figure 3 for example. Therefore, the teachings of Benne et al. are only applicable to H1N1 and H3N2 influenza virus A strains and are not relevant to influenza types B or C (admitted by Benne et al. in the second full paragraph on page 340), much less any permutations that the influenza A type virus undergoes every year. In addition, Benne et al. teach "preincubation" of the specific viral strains with SP-A that results in a dose-dependent reduction of infectivity. It is unclear how this "preincubation" would correlate to how many infective virions one would have to come into contact with in a real-world situation and how much of a sufficient quantity of ambroxol would be required to induce the appropriate quantity of SP-A to neutralize those specific strains of influenza virus (H1N1 and H3N2), if those specific influenza virus strains were indeed contacted. While Benne et al. show a reduction in the number of influenza virus A-infected cells in the presence of SP-A, see Figure 4, this is no indication or demonstration commensurate with the instant claim requiring "preventing infection".

Therefore, it is maintained that the instant invention would require an undue quantity of experimentation to use the invention commensurate with the scope of the claim for reasons of record.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on M-F 5:30 AM-3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/  
Primary Examiner  
Art Unit 1619